

US EPA ARCHIVE DOCUMENT

EPA Reviewer: M. Hashim

Date: May 17, 2006

Risk Manager (EPA): 25

STUDY TYPE: Acute Oral Toxicity – Rat; OPPTS 870.1100; OECD 425

TEST MATERIAL: SP1022 (Triclopyr-Triethylamine salt 14.8%), Lot #870IP506-2A, Gray granules

CITATION: Moore, G. (2006). Acute Oral Toxicity Study in Rats (Up and Down Procedure). Product Safety Laboratories, Dayton, NJ 08810, Study #: 18012 dated 1-30-06 MRID 46791903. Unpublished.

SPONSOR: SePRO Corporation, Carmel, IN 46032-4565.

EXECUTIVE SUMMARY: Up and Down Procedure- In an acute oral toxicity study (MRID 46791903), 3 female SD rats (Weight: 182-188 g; Source: Ace Animals, Boyertown, PA) were given a single oral dose of SP1022 (Triclopyr-Triethylamine salt 14.8%) by gavage at 5,000 mg/kg b.w. The test substance was prepared as a 30% w/w mixture in dist. Water. Initially only one test animal was dosed. The animal survived. Then additional two test animals were dosed in a sequence. Individual animal body weights were recorded. Cage-side observations were made at least once a day. Detailed clinical observations were conducted twice on the initial day of study and daily thereafter for the remainder of the study period. All animals were necropsied at the end of the study.

All test animals survived and gained weight throughout the study period. There were no clinical signs in any of the animals. There was no adverse effect on body weight gain. No gross lesions were observed at necropsy.

Oral LD₅₀ Females > 5,000 mg/kg

Based on the LD₅₀, SP1022 is classified as EPA Toxicity Category IV for acute oral toxicity.

This acute oral study is classified as acceptable. It does satisfy the guideline requirement for an acute oral study (OPPTS 870.1100; OECD 425) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

Test Seq.	Animal ID	Dose (mg/kg)	Short-term Result	Long-term Result
1	6081	5000	0	0
2	6101	5000	0	0
3	6102	5000	0	0

(0 = Survived)

Dose Recommendation: The limit test is complete.

The LD50 is greater than 5000 mg/kg.

A. Mortality – None.

B. Clinical observations - There were no apparent clinical signs in any of the animals. All test animals gained weight throughout the study.

C. Gross Necropsy - No gross lesions were observed at necropsy.

D. Reviewer's Conclusions: TRB agrees with the study author that the oral LD₅₀ Females > 5,000 mg/kg.